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Voluntary \_ Public

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#### **Brazil**

Post: Brasilia

# **Updated Plant and Label Registration Procedures for Dairy Products**

#### **Report Categories:**

Food and Agricultural Import Regulations and Standards - Certification

#### Approved By:

Clay Hamilton, Agricultural Minister Counselor

#### **Prepared By:**

Priscila Ming, Agricultural Specialist; Nicolas Rubio, Agricultural Attaché

#### **Report Highlights:**

Due to recent changes by Brazil in the procedures to register U.S plants that process dairy products for human consumption, FAS/ Brasilia prepared this comprehensive report with instructions for U.S. exporters to register plants and product labels. FAS/Brasilia updated Annex IV of this report due to recent changes by the Brazilian Ministry of Agriculture.

#### **General Information:**

#### 1. Step One - Plant Approval/Registration Process

All plants need to be approved and registered on Brazil's official list prior to starting the label registration process. Plant approval and registration requests must go directly to the Foreign Agricultural Service/Office of Agricultural Affairs in Brasilia (FAS/Brasilia). FAS/Brasilia requires a formal letter from the U.S. company to start the process of registering the U.S. processing plant. The letter must be completed using the <a href="Annex I">Annex I</a> format. Please be sure to include the table exactly as shown in the example.

#### Products Eligible to Export to Brazil

- Milk, powdered milk;
- Whey, Whey Protein Concentrate, Whey Protein Isolate;
- Milk Protein Concentrate, Milk Protein Isolate;
- Casein,
- Lactose:
- Cheese;
- Other dairy ingredients

#### 2. Step Two - New Label Registration Process

The new electronic system designed by the Brazilian Ministry of Agriculture, Livestock and Food Supply (MAPA) and the Department of Animal Products Inspection (DIPOA), can only be used to register new labels. Companies that already have labels registered in the old system do not need to resubmit them.

Once a U.S. plant is registered, a plant representative must submit an email request to FAS/Brasilia (<a href="mailto:priscila.ming@fas.usda.gov">priscila.ming@fas.usda.gov</a> and <a href="mailto:agbrasilia@usda.gov">agbrasilia@usda.gov</a>) with the information listed below, to request access to the system. FAS/Brasilia will then generate and submit a letter to MAPA (system) on behalf of the company.

- Name of the plant
- Plant number
- Address (complete address of the plant, including zip code)
- Name of the representative of the plant
- ID number (driver license or passport)
- Date of birth
- E-mail address
- Copy of the personal ID (driver license or passport) of the person that will be in charge for the registration process of that specific plant
- A letter in Portuguese from the plant authorizing this person to be the legal representative of the plant. Please use the attached template letter in Annex IV.

**Note:** The new legislation (see Annex II and Annex III) gives instructions on how to use the system. According to this new legislation and the new system, FAS/Brasilia can only request access to the system for U.S. representatives of the plants. FAS/Brasilia will not request access for Brazilian importers, consultants, or traders. The applicant must be in charge of the registration process and for securing all the files. This process is designed to maintain the integrity of confidential plant information. Under this process, MAPA will not request any additional certification information from the competent authority. FAS/Brasilia will not retain any personal identifiable information. If the registration information is lost, all labels will have to be re-registered.

FAS will notify the applicant when the information is submitted to MAPA. Once notified, the applicant can either complete the on-line process themselves or work with FAS/Brasilia by completing the following steps:

- 1. Once MAPA receives the information from FAS/Brasilia, the system will send a login and password to the U.S. authorized plant representative.
- 2. After receiving the login and password information, the U.S. plant representative can forward the login information to FAS/Brasilia (<a href="mailto:priscila.ming@fas.usda.gov">priscila.ming@fas.usda.gov</a> and <a href="mailto:agbrasilia@usda.gov">agbrasilia@usda.gov</a>) who in turn can complete the registration process on behalf of the company.
- 3. FAS/Brasilia will insert all the information in the system on behalf of U.S. companies.
- 4. As soon as the system approves the request, the representative indicated in the letter should receive an e-mail from the system. This representative will have the ability to insert the label applications into the system. At this stage, the designated representative can also nominate other representatives, importers, traders and or consultants to have access to the system and their files.

**Note:** The information from the U.S. plant and their representative will be kept confidential by MAPA. The U.S. company may define who will be the legal representative. After this phase is completed, companies can add as many people as they desire in the system and give them authority to manage the labels. FAS/Brasilia is not responsible if the representative of the company deletes anything in the system. FAS/Brasilia will not retain any personal identifiable information.

#### *NOTE:*

Please send a signed letter on company letterhead adhered to FAS Agricultural Counselor, currently Clay Hamilton (see example below):

US Department of Agriculture – USDA Foreign Agricultural Service Mr. Clay M. Hamilton Agricultural Counselor, American Embassy, FAS Av. das Nações, lote 3 70403-900 Brasilia, DF - Brazil

Dear Sir,

We kindly ask you to register the following U.S. dairy plant with the Brazilian Minister of Agriculture:

Número de Controle (Estabelecimento )/ Establishment number	Nome empresarial do estabeleciment o/ Establishment Name	Endereço completo do estabeleciment o (cidade/estado )/ Address of the Establishment (city/state and zip code) and telephone number	*Tipo de operação/ Type of operation (processin g or storage)	**Categoria( s) Category/ies	***Produto s/ Products	Espécie(s ) Species
			(Please check below the definitions on Item *)	(Please check below the definitions on item **)	(Please check below the definitions on item ***)	Example: please include species such as Bovine (BOV)

Note 1: Signed by the company's plant manager or someone responsible for the plant.

<u>Note 2</u>: Please send an electronic copy of the signed letter to FAS/Brasilia in order to proceed with the plant registration process with MAPA. The scanned letter must be sent to <u>priscila.ming@fas.usda.gov</u> and <u>agbrasilia@usda.gov</u>.

#### \* TYPE OF OPERATION:

Processing - PC; Stocking - ST

#### \*\* CATEGORIES:

#### Definitions:

- 1. CASEINS: Products resulting from the spontaneous precipitation of skim milk, or caused by curd or by mineral and organic acids.
- CASEINATES: Products obtained from the reaction of food casein or from the curd of fresh food casein with hydroxide solutions or alkaline salts or alkaline-earth or of food quality ammonia, and afterwards washed and dried, by way of technologically adequate processes.
- 3. MILK FLOURS: Products resulting from desiccation in proper conditions, of the mixture of milk with grains and legumes, whose starch has become soluble through the appropriate technique.
- 4. ANHYDROUS MILK FAT (BUTTER OIL): It is the greasy product obtained from cream or butter through the almost complete elimination of water and non-greasy solids, by way of technologically appropriate processes.
- 5. LACTOSE: It is the product obtained by the separation and crystallization of milk sugar.
- 6. BUTTERMILK: It is the liquid resulting from the churning of the cream for the manufacturing of butter, with or without added skim milk and biologically acidified by selected leaven, with partial lactose breakdown, and rich in lactic acid, protein and mineral salts.
- 7. BUTTERS: The greasy products obtained from the cream of milk by way of technologically appropriate processes.
- 8. MARGARINES: Greasy products in stable emulsion with milk or its components or by-products, and other ingredients, intended for human consumption with characteristic smell and taste. Milk fat, when present, shall not exceed the 3% (m/m) of total lipid content.
  - Mixtures of margarine with butter are not part of this category, since they will be included in the Milk Mixture category.
- 9. MILK BLEND: Covers dairy products obtained by mixing dairy ingredients with or without non-dairy ingredients.
- 10. MILK SAUCE: Dairy products subjected to technological processing, added to other dairy ingredients, spices and other approved food substances, intended for use in culinary preparations.
- 11. PERMEATES: Liquid products obtained by the withdrawal of milk protein and milk fat from milk (whole, skim or semi-skim) or the whey through a membrane filtration process.
- 12. CHEESE SNACK: Covers the fractionated cheeses presented in the form of a table of cold cuts, dried cheeses and breaded cheeses.
- 13. RAW MILK PRODUCTS: The raw materials which still need to undergo thermal treatment before being used in the preparation of products for consumption.
- 14. MILK POWDER PRODUCTS: This category covers, in addition to the products obtained by drying,

- those formulated from the mixture of other, already dried, dairy products.
- Considering its diversity of formulations, manufacturing processes and presentations, milk powder mixtures are not part of this category, since they will be included in the Milk Mixture category.
- 15. STERILIZED DAIRY PRODUCTS: Dairy products previously packed and subjected to a moist heat sterilization process, followed by immediate cooling, respecting the particularity of each product.
- 16. FERMENTED MILK PRODUCTS: Dairy products obtained through coagulation and decrease of pH by lactic fermentation through the cultivation of specific micro-organisms.
- 17. RENDERED DAIRY PRODUCTS: Dairy products obtained through mixture, fusion and emulsion, with heat treatment and emulsifying agents.
- 18. PARTLY DEHYDRATED MILK PRODUCTS: Dairy products obtained through partial dehydration of milk or milk by-products.
- 19. PASTEURIZED DAIRY PRODUCTS: Dairy products subjected to the pasteurization process.
- 20. PROTEIN DAIRY PRODUCTS: Dairy products obtained by the physical separation of caseins and whey proteins by membrane technology or other technological process whose equivalency is recognized by the Department for the Inspection of Products of Animal Origin of the Ministry of Agriculture, Livestock and Food Supply.
- 21. UHT MILK PRODUCTS: Dairy products subjected to the process of ultra-high temperature.
- 22. AGED CHEESES: Cheeses that have suffered the necessary and characteristic physical and biochemical exchanges of the variety.
- 23. MOLDY CHEESE: Cheeses aged by fungi.
- 24. NON-MATURED CHEESES: Cheeses ready for consumption shortly after having been manufactured.
- 25. GRATED CHEESES: The products obtained by crumbling or grating of the mass of one or up to four varieties of cheese of low and/or average humidity.
- 26. ULTRAFILTERED CHEESES: Cheeses obtained by processes of membrane technology.
- 27. RICOTTA: It is the product obtained from cheese serum albumin, with milk added up to 20% (twenty per cent) of its volume.
- 28. MILK DESSERT: It is the milk product ready for consumption, usually served after meals. Does not cover milk candies and condensed milk since they are included in the category of partly dehydrated milk products.

#### \*\*\* PRODUCTS:

MII	LK AND MILK PRODUCTS	
1	CASEINS	Acidic Food Casein;
	0125221 (6	Curd Food Casein;
		Lactic Food Casein;
		Industrial Casein
2	CASEINATES	Caseinate
		Milk Flour;
3	MILK FLOURS	Milk Flour with addition
	ANHYDROUS MILK FAT (BUTTER	Butter oil/ Anhydrous milk fat/ Fat of
4	OIL)	dehydrated butter
	012)	Raw lactose;
5	LACTOSE	Industrial lactose;
		Refined lactose
6	BUTTERMILK	Chilled buttermilk
		Butter;
7	BUTTER	High quality butter with salt;
		Unsalted Extra Butter
		Unsalted margarine;
8	MARGARINES	Margarine for industrial use;
		Margarine with salt
9	MILK BLEND	Caramel-based product
10	MILK SAUCE	Milk sauce
		Milk permeate;
11	PERMEATES	Milk whey permeate
10	CYPERGE GNA GYG	Dehydrated cheese;
12	CHEESE SNACKS	Breaded cheese
		Raw pre-processed skim milk;
		Raw chilled cream of milk whey for industrial
12	RAW DAIRY PRODUCTS	use;
13		Raw pre-processed whole milk of (animal
		species);
		Raw pre-processed whole milk
	POWDERED DAIRY PRODUCTS	Skimmed milk powder;
14		Skimmed milk powder of (animal species);
17	TOWNERED DAIRT I RODUCTS	Modified skimmed acidified milk powder;
		Cheese powder
15		Sterilized skimmed milk;
	STERILIZED MILK PRODUCTS	Sterilized standardized milk;
		Sterilized partially skimmed milk
16		Acidophilic milk with addition;
	FERMENTED MILK-BASED	Fermented milk;
	PRODUCTS	Fermented sweetened milk;
-		Fermented milk with addition
17	PROCESSED MILK PRODUCTS	Smooth cheese;
_ <u>-</u>	3	Cream cheese;

		Processed pasteurized cheese with addition
18	PARTIALLY DEHYDRATED MILK	Concentrated buttermilk;
	PRODUCTS	Concentrated milk whey;
	reducts	Milk based sweets for confectionery
		Pasteurized compound beverage;
19	PASTEURIZED MILK PRODUCTS	Pasteurized heavy cream with a high fat
19	ASTEURIZED WILK I RODUCTS	content;
		Pasteurized whole milk
	MILK PRODUCTS WITH PROTEIN	Isolated protein milk powder;
20	CONTENT	Isolated protein powdered milk whey;
	CONTENT	Lactalbumin
		UHT milk cream;
21	UHT MILK PRODUCTS	UHT flavored milk;
		UHT reconstituted whole milk
		Cheese type POIVRE D'ANE
22	AGED CHEESES	Cheese type PORT SALUT
		Cheese type EMMENTAL
		Cheese type CHAROLLES
23	MOLDY CHEESES	Cheese type GORGONZOLA
		Cheese type SAINT MARCELLIN
		Cheese type FRESH PROVOLONE
24	NON-MATURED CHEESES	Cheese type SERAC
		Cheese type FIOR DI LATTE
25	GRATED CHEESES	Grated cheese / grated cheese not dehydrated
26	ULTRA-FILTERED CHEESES	Ultra-filtered cheese
27		Smoked cottage with addition
	COTTAGE	Fresh cottage
		Fresh cottage with addition
28	MILK-BASED DESSERT	Milk-based dessert

#### \*\*\* PRODUCTS:

MII	MILK AND MILK PRODUCTS			
1	CASEINS	Acidic Food Casein;		
		Curd Food Casein;		
		Lactic Food Casein;		
		Industrial Casein		
2	CASEINATES	Caseinate		
3	MILK FLOURS	Milk Flour;		
3	WILK FLOURS	Milk Flour with addition		
4	ANIIVADOUS MILIZ EAT (DUTTED OIL)	Butter oil/ Anhydrous milk fat/ Fat of		
4	ANHYDROUS MILK FAT (BUTTER OIL)	dehydrated butter		
		Raw lactose;		
5	LACTOSE	Industrial lactose;		
		Refined lactose		
6	BUTTERMILK	Chilled buttermilk		

		T
7	D. M.	Butter;
	BUTTER	High quality butter with salt;
		Unsalted Extra Butter
8		Unsalted margarine;
	MARGARINES	Margarine for industrial use;
		Margarine with salt
9	MILK BLEND	Caramel-based product
10	MILK SAUCE	Milk sauce
4.4	DED MEATER	Milk permeate;
11	PERMEATES	Milk whey permeate
10	CHARGE GNA CARG	Dehydrated cheese;
12	CHEESE SNACKS	Breaded cheese
		Raw pre-processed skim milk;
		Raw chilled cream of milk whey for industrial
		use;
13	RAW DAIRY PRODUCTS	Raw pre-processed whole milk of (animal
		species);
		Raw pre-processed whole milk
		Skimmed milk powder;
		Skimmed milk powder, Skimmed milk powder of (animal species);
14	POWDERED DAIRY PRODUCTS	Modified skimmed acidified milk powder;
		Cheese powder
1.5		Sterilized skimmed milk;
15	STERILIZED MILK PRODUCTS	Sterilized standardized milk;
		Sterilized partially skimmed milk
	FERMENTED MILK-BASED PRODUCTS	Acidophilic milk with addition;
16		Fermented milk;
		Fermented sweetened milk;
		Fermented milk with addition
	PROCESSED MILK PRODUCTS	Smooth cheese;
17		Cream cheese;
		Processed pasteurized cheese with addition
	PARTIALLY DEHYDRATED MILK PRODUCTS	Concentrated buttermilk;
18		Concentrated milk whey;
		Milk based sweets for confectionery
	PASTEURIZED MILK PRODUCTS	Pasteurized compound beverage;
19		Pasteurized heavy cream with a high fat content;
		Pasteurized whole milk
	MILE DDODLICTS WITH DDOTEIN	Isolated protein milk powder;
20	MILK PRODUCTS WITH PROTEIN	Isolated protein powdered milk whey;
	CONTENT	Lactalbumin
21	UHT MILK PRODUCTS	UHT milk cream;
		UHT flavored milk;
		UHT reconstituted whole milk
		Cheese type POIVRE D'ANE
22	AGED CHEESES	Cheese type PORT SALUT
		Cheese type EMMENTAL
		Cheese type CHAROLLES
23	MOLDY CHEESES	Cheese type CHAROLLES  Cheese type GORGONZOLA
43		Cheese type GORGONZOLA  Cheese type SAINT MARCELLIN
		Cheese type SAINT WANCELLIN

24	NON-MATURED CHEESES	Cheese type FRESH PROVOLONE Cheese type SERAC Cheese type FIOR DI LATTE
25	GRATED CHEESES	Grated cheese / grated cheese not dehydrated
26	ULTRA-FILTERED CHEESES	Ultra-filtered cheese
		Smoked cottage with addition
27	COTTAGE	Fresh cottage
		Fresh cottage with addition
28	MILK-BASED DESSERT	Milk-based dessert

#### Annex II



#### MINISTRY OF AGRICULTURE, LIVESTOCK AND SUPPLY

Department of Inspection of Animal Origin Products - DIPOA Esplanada dos Ministérios, Bloco D, Anexo Ala A, 4º Andar, Sala 401, - Bairro Zona Cívico-Administrativa, Brasília/DF, CEP 70043900

Telephone: (61) 3218-2014/2684 and Fax: - http://www.agricultura.gov.br

Official Letter-Circular no. 1/2017/DIPOA-SDA/SDA/MAPA

Brasília, January 16<sup>th</sup>, 2017

To

SIPOA/SISA/SIFISA Heads

Servants acting in the Federal Inspection Service

Legal responsible individuals of registered (SIF) and listed (ER) establishments

Foreign Health Authorities with view to the legal responsible individuals and export establishments for Brazil

Subject: Registration of animal origin products. Change to procedures, communicates. Dear Sirs.

The DEPARTMENT OF INSPECTION OF ANIMAL ORIGIN PRODUCTS - DIPOA/SDA/MAPA communicates that from **18/01/2017** the registration of animal origin products will start to be conducted in a PGA, Agriculture and Cattle Raising Management Platform, system in module **PGA/SIGSIF.** This change will cover all the registrations of animal origin products, whether of a registered (SIF), listed (ER) or foreign (EE) establishment in compliance with the provisions of Decree no. 30.691, of March 9<sup>th</sup>, 1952, amended by Decree no. 8.681, of February 23<sup>rd</sup>, 2016.

All the inclusions of applications for the registration of animal origin products in the current system, Federal Inspection Service's Management Information Service – SIGSIF, and those submitted in paper forms (specifically in case of ER), **must be suspended as of that date.** 

The applications for the registration of regulated products must be rejected by SIF or by

SIPOA/SISA/SIFISA and the establishment must be guided to proceed with new insertion at PGA/SIGSIF.

The applications for the registration of <u>standardized products</u>, those requiring previous approval by DIPOA, and which have been entered at SIGSIF before that date, will be analyzed on a normal basis. All the application for the registration of animal origin products of foreign establishments (EE) already submitted in paper forms will be analyzed on a normal basis.

As presented above and seeking for the lowest impact as possible in the implementation of the significant amendments communicated above, we hereby emphasize that:

- 1. In order to obtain the first access, the user must use the link: <a href="http://sistemasweb.agricultura.gov.br/pages/PGA-SIGSIF.html">http://sistemasweb.agricultura.gov.br/pages/PGA-SIGSIF.html</a>
- 2. For non-registered users, **the first access to the system** will be granted/authorized by MAPA upon request by the interested party, and evidence of bond with the establishment. Such bond must be evidenced by presenting the company's documentation indicating the users as being its representatives at PGA/SIGSIF and the user's ID (digitalized copy), if applicable accompanied by a vernacular translation;
- 3. The access will be granted by the State Managers of PGA/SIGSIF of by the Management Support Division DSG/DIPOA;
- 4. The first access must be requested by the company's legal representative (SIF, ER or EE) in the "External Access Control Manager" profile, because the referred first user registered for each establishment will be responsible for releasing the access to the other users to be bond to that SIF, ER and/or EE:
- 5. The REGULATED products will be registered in the form of filing by entering the data requested by the PGA/SIGSIF system;
- 6. The STANDARDIZED products, those without regulation, will be registered upon previous approval by DIPOA;
- 7. In order to insert the product registration, the search must be started by consulting the **type of establishment (SIF, ER or EE)**, **establishment (corporate name)** and **standardized product**;
- 8. For some products with specific attributes, some files must be mandatorily attached so that the registration can be made effective. For example: For organic products, the Certificate of Organic, for products with geographical indication, the designation of Origin, among others. The file name is standard and the company must attach the corresponding file;
- 9. In the composition tab, the ingredients were classified as ADDITIVES, AROMAS, SINGLE or MIX. If the ingredient is composed of a mixture of at least 2 ingredients, it must be classified as MIX, the ingredients which compose such MIX must be described;
- 10. Once the unit of weight has been chosen for the ingredients, the system does not allow a change to the unit of weight between the entered ingredients (For example: if it is entered in grams, all the ingredients must be entered in grams, the insertion of liters or kilos will not be allowed). In the composition field, the disposition of the ingredients will be automatically ordered in a descending order of amounts, regardless of the type of ingredient (this system may be different from the order show on the label);
- 11. There's a need to bind the entered label to the packages;
- 12. For the registration of a product with more than one sketch, all the sketches must be attached to a single file so that they are considered for legal purposes.

#### **Annex III**

SECRETARY OF AGRICULTURE AND CATTLE RISING DEFENSE NORMATIVE INSTRUCTION No. 1, OF JANUARY 11<sup>th</sup>, 2017

THE SECRETARY OF AGRICULTURE AND CATTLE RAISING DEFENSE, DEPUTY, OF THE MINISTRY OF AGRICULTURE, LIVESTOCK AND SUPPLY, in the use of the attributions granted to him by art. 18, subparagraph II, letter "I", and art. 53, both of Attachment I of Decree no. 8.852, of September 20<sup>th</sup>, 2016, considering the provisions of Law no. 1.283, of December 18<sup>th</sup>, 1950, in Decree no. 30.691, of March 29<sup>th</sup>, 1952, and what is contained in Process no. 21000.021334/2016- 62, resolves: Art. 1<sup>st</sup> The procedures for the registration, renewal, amendment, audit and cancellation of the registration of animal origin products produced by establishments registered or listed in the Federal Inspection Service - SIF, and by foreign established authorized to export to the country, are established. Art. 2<sup>nd</sup> The procedures for the registration, renewal, amendment, audit and cancellation of registration, addressed by this Normative Instruction, must be conducted by the Department of Inspection of Animal Origin Products of the Ministry of Agriculture, Livestock and Supply's Secretary of Agriculture and Cattle Raising Defense – DIPOA/SDA/MAPA

Sole paragraph. DIPOA may designate Federal Fiscal Agriculture and Cattle Raising Auditors who perform inspection activities of animal origin products in the Federal Agriculture, Livestock and Supply Superintendencies to conduct the analysis of registration, renewal, amendment applications and registration audit.

- Art. 3<sup>rd</sup> The procedures for the registration, renewal, amendment and cancellation of registration addressed by this Normative Instruction must be electronically conducted in the computer system available at MAPA's website: <a href="www.agricultura.gov.br">www.agricultura.gov.br</a>.
- § 1<sup>st</sup> The access to the electronic system will be granted upon previous authorization, by means of personal identification.
- § 2<sup>nd</sup> It is the user's sole responsibility to maintain the confidentiality of the password part of his/her electronic identification, being that it's not accepted, under any circumstances, the allegation of its undue use.
- § 3<sup>rd</sup> The directions for the use of the computer system are made available at MAPA's website. Art. 4<sup>th</sup> The request for accessing the computer system, for national producing establishments, must be performed by its legal representative by means of electronic register.
- § 1<sup>st</sup> For the purposes of registry, the following documents must be submitted by electronic means:

I – copy of the establishment's by-laws; and

II – copy of the legal representative's personal ID.

§ 2<sup>nd</sup> The legal representative must authorize the users designated to conduct the activities related to the registration, amendment, renewal and cancellation of registration.

Art. 5<sup>th</sup> The request for accessing the computer system, for foreign producing establishments, must be performed by its legal representative by means of electronic register.

§ 1<sup>st</sup> For the purposes of registry, the following documents must be submitted by electronic means, accompanied by vernacular translation:

I – copy of the document issued by the authority of the country of origin indicating the establishment's representative, for the purposes addressed by this Normative Instruction; and

II – copy of the personal ID of the establishment's legal representative.

§ 2<sup>nd</sup> The representative must authorize the users designated to conduct the activities related to the registration, amendment, renewal and cancellation of registration.

Art. 6<sup>th</sup> The national producing establishment's legal representative and the foreign producing establishment's representative must maintain the list of its respective system users updated.

Art. 7<sup>th</sup> The registration application must be conducted by the national or foreign producing establishment, accompanied by the following information and documentary elements in Portuguese language:

I – establishment identification;

II – product identification and characterization data;

III – product composition indicating the ingredients in descending order of amount;

IV – description of the manufacturing process;

V – opinion of the health regulatory body about the use of functional or health property allegations, when such allegations are contained on the label;

VI – thermal processing calculation for canned products, submitted to commercial sterilization for each type of package and product weight;

VII – reliable and legible reproduction of the label, in its original colors, indicating its dimensions and size of the characters of the mandatory information of the label; and

VIII – other documents required by the legislation for granting the registration of specific products.

§ 1<sup>st</sup> The description of the manufacturing process must be performed on an ordered way and include the purchase or receipt of raw material, processing contemplating the time and temperature of the technological processes used, packaging, storage and preservation of the product, as well as the specifications providing the distinctive characteristics of the product.

§ 2<sup>nd</sup> The label may present variations in its dimensions, colors and drawings and all the variations must be sent for the purposes of registration.

§ 3<sup>rd</sup> Non-formulated meat products must have a single registration number whenever they are submitted to the same manufacturing process.

§ 4<sup>th</sup> Fish in nature must have a single registration number for the several species and presentation forms, whenever it is submitted to the same manufacturing process.

§ 5<sup>th</sup> The label printed exclusively in foreign language, of products intended for the international trade, must be registered along with its vernacular translation.

§ 6<sup>th</sup> Compound ingredients must have their components and amounts described.

Art. 8<sup>th</sup> The registration and amendment of the registration of products not covered by Decree no. 30.691, of March 29<sup>th</sup>, 1952, or in its complementary acts, must be performed upon previous approval of the information and documents contained in article 7<sup>th</sup> of this Normative Instruction. Art. 9<sup>th</sup> The registration and amendment of the registration of products covered by Decree no. 30.691, of March 29<sup>th</sup>,

1952, or in its complementary acts, must be performed by providing the information and documents contained in article 7<sup>th</sup> of this Normative Instruction.

Sole paragraph. The list of products provided for in the caput of this article is made available in the computer system addressed by this Normative Instruction.

- Art. 10. The products intended for export can be manufactured and labeled according to the requirements of the country they are intended to.
- Art. 11. The product registration must be renewed every 10 (ten) years upon request by the establishment before they are expired.
- Art. 12. No change to the formulation, manufacturing process or label can be performed without previous update of the registration at DIPOA.
- Art. 13. The information contained in the product registration must exactly correspond to the procedures conducted by the establishment.
- Art. 14. The number to be assigned to the product registration must be generated by the establishment and automatically controlled by the computer system.
- § 1<sup>st</sup> Each number corresponds to a registration, being that its reuse is not allowed.
- § 2<sup>nd</sup> The registration number must be separated by bars from the establishment's registration or control number.
- Art. 15. The change to the product sale denomination implies the application of a new registration.
- Art. 16. DIPOA must conduct a product registration audit in order to verify the compliance with the legislation and the conformity of the documents and information provided by the establishment.
- Art. 17. When non-conformities related to the product registration are found, DIPOA must notify the national producing establishment or the health authority of the country of origin of the foreign producing establishment, specifying the non-conformity and, if applicable, the deadline for its correction.

Sole paragraph. The failure to comply with the measures determined by DIPOA implies the cancellation of the registration.

Art. 18. The cancellation of the registration is automatic in the following situations:

I - if requested by the establishment; and

II – due to the expiration of the registration without application for renewal.

Art. 19. The registration must be cancelled in case of failure comply with the provisions of Law no.

1.283/1950, of Decree no. 30.691/1952, and of the other applicable rules.

Art. 20. The registrations already existing on the date this Normative Instruction is published will remain valid for 10 years from the date it is granted.

Sole paragraph. Any renewal or amendment implies new registration, upon compliance with the procedures established in this Normative Instruction.

Art. 21. DIPOA may request, during the registration process or subsequently, the original of the documents electronically presented by the applicant.

Sole paragraph. The original documents must be preserved for the validity of the product registration.

- Art. 22. DIPOA may request additional information or documents in order to subsidize the analysis of the registration application, amendment and audit.
- Art. 23. The cancellation of the registration does not impair the application of the fiscal actions and applicable penalties resulting from the violation to the legislation.
- Art. 24. This Normative Instruction comes into force on the date it is published.
- Art. 25. Ordinance SIPA no. 9, of February 26<sup>th</sup>, 1986 is revoked.

Signed by Dr. JORGE CAETANO JUNIOR/DOU 18/01/2017

Annex IV (Updated)

LETTER HEAD OF THE COMPANY

Portuguese Version

# **DECLARAÇÃO**

# REPRESENTANTE DE ESTABELECIMENTO ESTRANGEIRO PERANTE A AUTORIDADE SANITÁRIA DO BRASIL

Diante da publicação da Instrução N	ormativa N° 01, a	e 11 de janeiro de 2	.ui/ aa Sec	retaria de Defesa
Agropecuária – SDA/MAPA, que es	stabelece os proced	dimentos para regis	tro, renovaç	ção, alteração,
auditoria e cancelamento de registro	de produtos de or	igem animal produz	zidos por es	stabelecimentos
registrados ou relacionados no Servi	iço de Inspeção Fe	deral - SIF, e por es	stabelecime	ntos estrangeiros
habilitados a exportar para o Brasil,	vimos por meio de	este indicar o (a) ser	nhor (a)	*complete
name/the same as the document*	, portador do	*descripti	ion of the d	ocument, passport,
or driver license * "number*		, e-mail		
,como	representante do	estabelecimento est	rangeiro	*name of the
establishment*/must be the same as	the Brazil list of a	pproved plants	, sob núme	ro de controle
veterinário* plant number * , loo	calizado no país Es	stados Unidos da Ai	mérica, par	a acesso à
Plataforma de Gestão Agropecuária	- PGA.			
Assinatura e carimbo do representar	nte legal do estabel	ecimento estrangei	ro	

LETTER HEAD OF THE COMPANY

**English Version** 

### **DECLARATION**

## REPRESENTATIVE OF A FOREIGN ESTABLISHMENT TO PRESENT TO THE SANITARY AUTHORITY OF BRAZIL

In view of the publication of	Normative Instructio	n No. 01 of January 11, 2017 of the Agricultural		
Defense Secretariat - SDA / ]	MAPA, which establi	shes the procedures for registration, renewal,		
alteration, audit and cancella	tion of registration of	products of animal origin produced by registered		
establishments or related in the	he Federal Inspection	Service - SIF, and by foreign establishments qualified		
to export to Brazil, we hereby	y indicate the	* full name/the same as described in the document *		
, bearer of	*descriptio	n of the document, passport, or driver license **		
number	, e-mail	, as representative of the		
foreign establishment*	establishment name	/ must be the same as the Brazil list of approved plants		
*, under veterinary control number _*plant number*, located in the country United States of				
America, for access to the Pla	atform of Agricultura	l Management - PGA.		
Signature and Stamp of the le	egal representative of	the foreign establishment		